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## Hungary

### Biotechnology

### Annual Report

### 2005

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**Report Highlights:**

Hungary's biotechnology policy for feed corn production, corn seed production, and soybean product (soybean meal) imports negatively impacts U.S. exports to Hungary. Field corn and seed corn production (about one fifth of the EU's corn crop) is dominated by American varieties. Four corn varieties passed the evaluation process and are waiting approval, two others are still under field trials. In January 2005, the GOH imposed a moratorium on the varieties of the MON 810 corn event. Legal and technical debates about the moratorium and coexistence regulation (in preparation) may hamper the commercialization of biotechnology crop varieties in Hungary over the next few years.

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## Executive Summary

Hungary's biotechnology policy for feed corn production, corn seed production, and soybean product (soybean meal) imports negatively impacts U.S. exports to Hungary. Field corn and seed corn production (about one fifth of the EU's corn crop) is dominated by American varieties. Four corn varieties passed the evaluation process and are waiting approval, two others are still under field trials. In January 2005, the GOH imposed a moratorium on the varieties of the MON 810 corn event. Legal and technical debates about the moratorium and coexistence regulation (in preparation) may hamper the commercialization of biotechnology crop varieties in Hungary over the next few years.

## Biotechnology Trade and Production--Status of Product Approvals

No biotechnology crop varieties are produced in Hungary. Three varieties have gone through field trials and are waiting registration, including:

Field trials finished in 2003:

MEB 470 BT (DK 440 BTY) MON 810 code number corn borer resistant (MONSANTO)

NX 3035 (Alpha BT) Bt11 code number corn borer resistant (Syngenta)

X 0987ZT MON 810 code number corn borer resistant (Pioneer Hi-Bred Rt.)

The Ministry of Agriculture and Rural Development (MARD) refused to approve the registration of the above varieties because coexistence regulation is not yet in place.

Additional corn varieties subject to field trials include:

MEB 471 RR (DK 440 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

MEB 391 RR (DK 391 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

X1019VT BT code number corn borer resistant (PIONEER Hi-Bred Rt.)

On January 20, 2005, the Government of Hungary (GOH) imposed a moratorium on corn varieties containing the MON 810 event. The moratorium went into effect by a Minister's Decree, and the legal paperwork for the moratorium is now in Brussels for official review.

The four main reasons for the moratorium were the following:

- 1). The negative results of an environment effect study. The research carried out in Hungary under the direction of the Plant Protection Institute of the Hungarian Academy of Sciences focused on genetically modified maize DK 440 BTY containing the genetic construction YieldGard™ MON 810. Laboratory and small-scale parcel field experiments showed that the long-term presence of the plant might have adverse effects on the ecosystem. (*Darvas et al. (2003) EFFECT OF POLLEN OF DK-440-BTY (YIELDGARD) BT MAIZE ON THE LARVAE OF INACHIS IO L. (NYMPHALIDAE)* Hungarian Academy of Sciences, Plant Protection Institute, Ecotoxicology Department, Budapest)
- 2). The need to repeat the late 1990s EU trials using contemporary methodology for this event.
- 3). The specific ecological conditions of the "Pannonian biogeographic region" (a region containing parts of Hungary, Austria, and Slovenia) questions the validity of risk assessment

based on the ecosystems of the older Member States, owing to its different environmental features.

4). Hungary has no coexistence regulation yet.

Hungary is an active participant in the development of biotechnology crops at the basic science level, as well as in the research of the environmental, feeding, etc. effects of these crops in cooperation with other countries.

Hungary does not import biotechnology crops, but imports soybean meal, peanut butter, sauces and other products containing biotech raw materials.

### **Biotechnology Policy--Regulatory Framework**

In the case of green (agricultural) biotechnology, the MARD takes the lead concerning the cultivation, importation, and processing into food/feed. The Hungarian Food Safety Authority (HFSA) under the Ministry of Health (MH) is the top umbrella organization, but most of the administrative responsibilities and the institutional background belong to the MARD. The Ministry of Environment and Water Management (MEW) handles certain biotechnology regulation portfolios and also participates in the work of the Biotechnology Committee (BC). MH is responsible for the red biotechnology (medicinal use), and the Ministry of Economy and Transport (MET) handles foreign trade and strategic investment affairs. Both the MH and the MET are advocates of biotechnology as the key to further economic development but firmly differentiate between red (thought of positively) and green (thought questionably) biotechnology.

The Biotechnology Committee (BC) has a key role in evaluating the applications (new varieties, genes, etc.) although the approval is formally made by the MARD. The Hungarian Academy of Science (MTA) may delegate five members, the relevant Ministries (MARD, MET, MH, MEW) and the Ministry of Education delegate one each, and NGOs may nominate seven delegates (including one by the pro-biotech Zoltan Barabas Biotechnology Association) to the 17 member BC. Civil Servants (government employees) are not members of the BC. Ministries nominate scientists or experts from 'think tanks' belonging to their Department. The "independent" BC sets its own rules, supposing that the question is not regulated in the Act No. XXVII. of 1998 On Biotechnology or elsewhere (e.g. 111/2003. (XI.5.) Order of Ministers of MARD, MET, MH, and MEW on Genetic Modification and Like Processes, and their Inspection Authorities).

Administrative and service charges of the Committee and other authorities inspecting biotechnology experiments are set in the 138/2004. (IX.23) Order of the Minister of MARD on the administrative and Service Fees for the Approval of Gene-technology Activities.

Regulatory decisions may be influenced by different political factors, including:

- EU market orientation of Hungary's corn and corn seed production. Traditionally strong cooperation with Austria and Germany, main opponents of GMOs.
- The Hungarian consumer is pragmatic, but domestic and international green organizations are increasingly active in Hungary.
- Politicians, government officers, journalists and sometimes scientists are shy to express their opinions about biotechnology or even participate in topical seminars.

### **Biotechnology Research**

Besides testing biotechnology crop varieties, Hungarian biotechnology laboratories are dealing with the analysis of different GMO materials. Use of these biotechnology materials (for variety field test or any other feeding, environmental effect, etc. trials) must also be approved by the BC. Lists of biotechnology materials and programs are available at the website of the Godollo Agricultural Biotechnology Center ([www.abc.hu](http://www.abc.hu)) and the website of the EU Commission, Directorate General, Joint Research Centre (<http://biotech.jrc.it>) quoted in ANNEX I.

According to a Biotech Committee Decision, stacked events are taken for new events, considering possible cross effects.

### **Coexistence Regulation**

The MARD finished the drafting and first panel discussions of the Hungarian coexistence regulation in June 2005. The new piece of legislation will be a chapter of the amendment to the Act on Biotechnology. The draft coexistence regulation has been sent for Commission approval. The drafting period (first half of 2005) included vivid discussions at different government and NGO forums. Representatives of the biotechnology industry and the Biotechnology Association participated in the work of the Coexistence Working Committee. The responsible Ministries are also drafting the application orders of the coexistence regulation.

### **Labeling rules**

Act No LXXXII of 2003 on Food (AF) is a general, "umbrella" piece of legislation. The Act does not contain the domestic versions of EU (European Council or Commission) directives, so it does not need to be revised whenever any EU directive is changed. The domestic directives are contained in the **Hungarian Food Codex (HFC)** or other separate legal rules (such as legislation for Wine, for Mineral Water, and for Meat and Meat Products). General prescriptions of the Act must be applied together with HFC directives and other corresponding regulations.

All kinds of food, including food imported for commercial sale, fall under the ruling of the Act. (Products from other EU member countries are considered as domestic products (§7. (2)) See the AF in English at [http://www.fvm.hu/files/elelmiszeripar/elszi\\_5\\_en.pdf](http://www.fvm.hu/files/elelmiszeripar/elszi_5_en.pdf)

Other corresponding regulations include:

#### **19/2004. (Feb 26.) Order of the Min of Agr-Min of Health-Min of Economy On labeling of Foodstuffs**

#### **138/2004 (Sep 23.) Order of the Min of Agriculture On the administrative and Service Fees for the Approval of Gene-technology Activities**

e.g. -Fees for the approval of commercial sales of GMOs and products thereof

-Fees for the approval of the export-import trade of above products

#### **142/2004. (Sep 30.) Order of Min of Agr-Min of Economy On Some Rules of Gene-technology Activities in Agriculture and Industry**

e.g. Labeling of products containing GMOs (above the threshold level).

Hungary is not an importer of biotech products, excluding animal feed. Plant propagation materials (seeds) go through systematic sampling and laboratory analyses. However, for feed and food, where the exporter must declare the quality of the product, only random sampling takes place. The breakdown of samples analyzed in the official biotech testing laboratory of the Agricultural Biotechnology Center at Godollo in 2004 included the following:

62%	Corn
10%	Soybean
10%	Feed
9%	Processed soya
7%	Processed corn
2%	Other products

Source: [www.abc.hu/](http://www.abc.hu/) under Services, than State laboratory for GMO testing.

### **Cartagena Biosafety Framework**

Hungary has ratified the Biosafety Protocol. The legislation is the CIX./2004. Act on the Promulgation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The implementation rules of the Act have not yet been prepared.

### **Capacity Building and Outreach**

Post has sponsored government officers, scientists and journalists on agricultural biotechnology programs in the US through the Cochran Fellowship Program over the past few years.

The International Visitor Program of State Department has also been used for sending a Hungarian government official to the United States as part of an outreach activity.

In 2005, the USDA/FAS Biotechnology unit co-sponsored the travel of a Hungarian journalist to participate at the congress of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in Singapore, March 18-24, 2005. The goal of the Hungarian participation was to facilitate the establishment of a Hungarian 'node', a national knowledge center, of the ISAAA.

## ANNEX

## I. Deliberate releases, Plants – Hungary, 2005

Notification Number	State	Publication	Name of Institution or Company	Project title
<a href="#">B/HU/05/01/4</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trial program of genetically modified maize resistant to certain Lepidopteran and Coleopteran insects and tolerant to two herbicides (59122x1507xNK603 maize)
<a href="#">B/HU/05/01/5</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trials program of genetically modified maize resistant to certain Coleopteran insects and tolerant to two herbicides (59122xNK603 maize)
<a href="#">B/HU/05/01/6</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trials program of genetically modified maize varieties resistant to certain Lepidopteran and Coleopteran insects and tolerant to glufosinate-ammonium herbicide (1507x59122 maize)
<a href="#">B/HU/05/02/1</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trial program of genetically modified maize varieties resistant to certain Lepidopteran insects and tolerant to two herbicides (1507xNK603 maize)
<a href="#">B/HU/05/02/2</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trials program of maize varieties resistant to certain Coleopteran insects and tolerant to a herbicide (59122 maize)
<a href="#">B/HU/05/02/4</a>	Hungary	24/05/2005	Pioneer Hi-Bred Hungary Ltd.	Field trial program for the testing of biotech maize tolerant to glyphosate herbicide (E5846.49.7.12 and

				E5846.53.9.4)
<a href="#">B/HU/05/01/1</a>	Hungary	16/02/2005	Pioneer Hi-Bred Hungary Ltd.	Trial program for the testing of 1507 biotech maize varieties resistant to certain Lepidopteran insects and tolerant to glufosinate-ammonium herbicide
<a href="#">B/HU/05/01/2</a>	Hungary	16/02/2005	Pioneer Hi-Bred Hungary Ltd.	Program of field agronomic trials and registration trials with NK603 maize varieties tolerant to glyphosate herbicide
<a href="#">B/HU/05/01/3</a>	Hungary	16/02/2005	Pioneer Hi-Bred Hungary Ltd.	Program of field agronomic trials and registration trials with NK603xMON810 maize varieties tolerant to glyphosate herbicide and resistant to certain lepidopteran insects